





#### **EPA Is a Risk-Based Agency**

- Agency manages risk to human health and the environment – complex decisions require sound information
- Risk assessment plays a key role in identifying important hazards and in developing management strategies
- Risk is considered a function of exposure and hazard (or toxicity), both of which have inherent uncertainties



# **Supporting Agency Decisions**

- EPA recognizes many new risk situations where characterizing uncertainty important for good decisions
  - -Priority setting
- -Sustainability
- -Regulatory options
- -Homeland security
- Additional utility for VOI and research planning
- Will help Agency meet its transparency goals



#### **Microbial Risk Assessment in EPA**

- · Multiple programs and media
  - -Pesticides
  - -Water
  - -Solid Waste
- · Decision makers are confronted with
  - -Complex problems
  - -Complex assessments
  - -Limited data
  - -Short timelines





#### **Chemical vs. Microbial Uncertainties**

- Hazard Identification
- -Methodology
- Dose-response relationships
  - -Reconstructing exposure from epidemiological data
- Species extrapolation
  - -Microbial specificity
- Environmental persistence
  - -Decay kinetics
- · Sensitive groups or populations
- -Modes of action



## **Increasing Analysis of Uncertainty and** Variability: Exposure

- · Almost 10 years of experience in quantitatively analyzing uncertainty and variability in exposure
- · Some challenges remain:
  - -Data choices
- -Model uncertainty
- -Propagating uncertainty



## **Increasing Analysis of Uncertainty and Variability: Toxicity**

- · New emphasis on uncertainty and variability in toxicity values
- · Some resistance to quantifying uncertainty
- · Recent scientific advice to the Agency
  - -SAB (Ethylene Oxide)
  - -NAS (Dioxin, TCE)



## **General Advice From Scientific Community**

- · Increase quantitative characterization of uncertainty in dose-response assessments
- · Consideration and use of multiple data sets and endpoints
- · Explicit reporting of criteria for data selection
- · Quantitative presentation of alternative low dose extrapolation models



# **Supporting Enhanced Consideration** of Uncertainty

- · Efforts primarily focusing on chemical risk assessment
- · Need to apply knowledge to microbial issues
- Some EPA product and activities
  - -Risk Characterization Handbook
  - -NAS/Institute of Medicine project
  - -Probabilistic Risk Assessment workgroup



#### **Risk Characterization Handbook**

- · Principles of
  - -Transparency
  - -Clarity
  - -Consistency
  - -Reasonableness
- · Risk Characterization helps decision makers
- -Achieve a better-informed decision
- -Understand the science
- -Build trust and credibility with staff, public and stakeholders





# **NAS/IOM Panel**

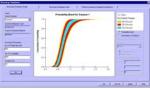
- · Panel provides independent advice
- Tasked with providing advice on how to improve decision-making under uncertainty
- Benefits
- -Tools
- -Communication -Implementation
- Panel has sought advice from
- -Agencies
- -Industry
- -Academia
- -Environmental groups
- Report expected in fall 2008



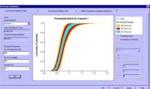
# **Advancing Probabilistic Assessment**

Office of Science Advisor Activity:

- White Paper on PRA Utility
- Case Studies
- · Compiling tools, methods, best practices
- Expanded training









**Thank You!** 



## **Looking to the Future**

- · Approaches to public health and environmental decisionmaking under uncertainty:
  - get beyond "we won't know how to use this information"
- Specific tools and methods for informing decisions with quantitative analysis reflecting uncertainty in risks of specific outcomes.
- Methods for communicating uncertainty in risk information to a range of interested parties including decision makers and citizens